

A. APPLICATION DATA SHEET: Not Applicable

B. SPECIFICATION:

An Intramedullary Nail (IM Nail) is inserted into the cortical bone. Standard interlocking technique is used to place each of the screws into the nail. However, these screws are headless (versus a headed screw used in current techniques). The screwdriver for placing the headless screw remains attached to this headless screw after insertion. A decision is made on the length of the outer screw (the one that encapsulates the headless screw) to be placed so that the intramedullary nail is kept at a fixed distance from the cortex of the bone.

The headless screw is then over drilled with a canulated drill. The canulated outer screw is then placed over the modular screwdriver and then over the headless screw. The outer screw engages threads on the nail, locking the outer screw to the nail. The opening of the nail may be tapered such that it allows the outer screw a perpendicular insertion to the nail. The screw may also be tapered to all interlock with the IM Nail.

Additionally, a small thin sleeve may be on the outer screw that will allow for centering the headless screw in the nail opening. This will eliminate the play of the headless screw within the nail. Upon surgeon's discretion, a similar outer screw can be placed from the contra lateral side where the anatomy will allow it. Having screws on opposing sides of the IM Nail, will help to center the nail and guarantee locking and increases cortical purchase of the screws.

C. TITLE OF INVENTION:

A new method of interlocking Intramedullary Nails (IM Nails) is to use headless screw for performing interlocking with the nail. A subsequent, canulated outer screw is placed such that it encapsulates this headless screw. The outer screw locks to the IM Nail and holds the headless screw in place to eliminate play in the screw-nail interface and result in a more stable form of fixation.

D. CROSS REFERENCE TO RELATED APPLICATIONS:

Provisional Patent Application #: 60/459,952 with a filing date of April 4, 2003
(submitted by inventor of this application)

Patent #6,019,761, dated February 1, 2000 suggests interlocking by using guidewire that goes in through the IM Nail holes, up or down the IM Nail and out the next hole.

Patent #6,524,314, dated February 25, 2003 suggests interlocking by using 2 lag screws and a locking screw through the IM Nail.

E. STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT: Not Applicable

F. REFERENCE TO SEQUENCE LISTING: Not Applicable

G. BACKGROUND OF THE INVENTION:
The current methods of fracture reduction are:

- Casts / braces
- Plates:
 - Conventional
 - Locking
- External fixation
- Intramedullary Nails

Intramedullary Nails have several advantages over other forms of fixation:

- they are less invasive than plates;
- they have a lower infection rate;
- nails are stronger than the plates;
- nails have a mechanical advantage compared to plates;
- the screws used with nails are more resistant to breakage due to the decreased moment arm;
- screws may be placed in different planes;
- nails have a high rate of union;
- nails allow for anatomic reduction;
- cast/braces immobilize the limb and do not allow early motion;
- external fixators have a risk of pin tract infections.

One of the current method of interlocking IM Nails is to solely use screws, which can result in loss of reduction because of the inherent play in screw-nail interface. A second way of

interlocking IM Nails is to cap the screw at the contra lateral cortex, which increases fixation in the cortical bone; however, does not help the screw-nail interface; additionally, pressure applied by the capping on one end may cause the distal end to move out of position. A third available way of interlocking IM Nails is to have the hole of the IM Nail lined with rubber to provide a more grippable material for the screws; however, the inherent play in rubber does not provide sufficient locking. The rubber lined IM Nails also have the possibility for foreign body reactions with flaking of the rubber.

This new design, with threaded guidewire in between the screws, locks the screw in place to eliminate this play and result in a more stable form of fixation.

Two other patented ways of interlocking IM Nails were found, however, neither are currently marketed:

- An interlocking Intramedullary Nail (patent #6,524,314, granted February 25, 2003) provides for a different mechanism, using 2 lag screws and a locking screw. This product is currently not marketed; however, this would be a difficult mechanism because there are only a couple of safe zones where screws can be placed. With the addition of 2 screws placed for fixation, it may be difficult to find safe zones. Additionally, they may cross thread early prohibiting further insertion.
- An interlocking Intramedullary Nail (patent #6,019,761, granted February 1, 2000) provides for interlocking by placing a guidewire through one screw hole up to and out of the next. This patent also relies on drilling holes versus already manufactured holes and dropping wires through the holes and using the screws to cause the wires to interlock to the screws. This patent has a completely different means by which the interlocking would occur and be enhanced.

This new mechanism, with the headless screw and outer screw, locks the screw in place to eliminate this play and result in a more stable form of fixation. A sleeve on the outer end of the screw will aid in centering of the screw. Additionally, the option of placing an outer screw on both sides of the IM Nail offers a possibly stronger fixation with increased ability to center the IM Nail.

H. BRIEF SUMMARY OF THE INVENTION:

This invention provides for a new method for locking Intramedullary Nails (IM Nails) with headless screws for performing interlocking with the IM Nail. The headless screw is over drilled with a canulated drill. A subsequent, outer screw is placed such that it encapsulates this headless screw. The outer screw engages threads on the nail, locking the outer screw to the nail. This method and design eliminates play in the screw-nail interface and result in a more stable form of fixation. The headless screw may also have a sleeve on the outer end which will aid in centering of the IM Nail. The outer screw may also be placed from the contra lateral side where the anatomy will allow it.

I. BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING:

Page 1: Diagram of Insertion of the first headless screw into Intramedullary nail

- 1.Cortical bone
- 2.Intramedullary Nail
- 3.Headless screw
- 4.Modulated screwdriver

Page 2: Diagram of over drilling around the headless screw with canulated drill.

- 1.Headless screw
- 2.Modulated screwdriver
- 3.Are of over drilling around headless screw
- 4.Intramedullary Nail

Page 3: Diagram of insertion and interlocking of outer screw to inner screw and Intramedullary Nail

- 1.Canulated outer screw
- 2.Optional sleeve with variable length
- 3.Dotted line showing canulated outer screw to be placed over headless screw
- 4.Engaged outer screw over headless screw
- 5.Place where outer screw interlocks with Intramedullary Nail
- 6.Intramedullary Nail
- 7.Placement of additional optional outer screw on the contra lateral side

J. DETAILED DESCRIPTION OF THE INVENTION:

The IM Nails and screws are manufactured with cobalt-chrome, titanium or other materials for strength and durability. The current methods do not address screw-nail interface locking and can cause loss in reduction. In this invention, the IM Nail is secured by headless screws and canulated outer screws that cap the headless screws; this will secure and eliminate movement of the screws to the IM Nail.

The screwdriver for placing the headless screw remains attached to this headless screw after insertion. A decision is made on the length of the outer screw (the one that encapsulates the headless screw) to be placed so that the intramedullary nail is kept at a fixed distance from the cortex of the bone. The headless screw is then over drilled with a canulated drill. The outer screw is then placed over the modular screwdriver and then over the headless screw. The outer screw engages threads on the nail, locking the outer screw to the nail. The opening of the nail may be tapered such that it allows the outer screw a perpendicular insertion to the nail. The screw may also be tapered such that it can also interlock with the IM Nail.

Additionally, a small thin sleeve may be on the outer screw that will allow for centering the headless screw in the nail opening. This will eliminate the play of the headless screw within the nail. Upon surgeon's discretion, a similar outer screw can be placed from the contra lateral side where the anatomy will allow it.

Current methods of interlocking IM Nails do not eliminate the screw-nail interface play. Therefore, current methods can result in loss of reduction of the fracture. This method and design in locking eliminates play in the screw-nail interface and results in a more stable form of fixation.

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M. DRAWINGS: see 3 pages attached

N. OATH OR DECLARATION: see attached form

O. SEQUENCE OF LISTING: Not Applicable

P. OBTAINING A RECEIPT FOR DOCUMENTS MAILED TO USPTO:
Return postcard has been enclosed.